UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,628	04/27/2001	Joseph Roberts	023032/0108	9388

22428 7590 04/07/2005

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/842,628	ROBERTS ET AL.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-30 and 47-57* is/are pending in the application.

4a) Of the above claim(s) *24-30 and 47-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-53,56 and 57* is/are rejected.

7)☒ Claim(s) *54 and 55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This non-final Office action is responsive to the reply received November 23, 2004. Claims 1-23 and 31-46 have been canceled and claims 24-30 and 47-50 have been withdrawn. Claims 51-57 are under examination.

Terminal Disclaimer

The terminal disclaimer filed on November 29, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,312,939 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC §§ 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 51-53, 56 and 57 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over "Roberts" (Journ Bio Chem (April 1976) Vol. 251, No. 7 pp. 2119-2123 in view of U.S. Patent No. 5,232,840 to Olins.

Claims 51-53, 56 and 57 are drawn to a method of producing a therapeutically suitable glutaminase comprising culturing a "recombinant" microorganism that has a nucleotide sequence that

encodes a therapeutically suitable glutaminase, and collecting therapeutically suitable glutaminase from the cultured microorganism. The claims further provide that the therapeutically stable glutaminase may comprise (a) *Pseudomonas* glutaminase, or (b) a glutaminase having a Km of 10-6 to 10-4 which is active in human sera.

Roberts anticipates claims 51-53 and 56-57 in that it discloses a method of producing glutaminase comprising isolating *Pseudomonas* 7A, growing it in culture, and isolating glutaminase enzyme from a cell homogenate of the *Pseudomonas* 7A using ammonium sulfate precipitation (see e.g. p. 2120, ¶¶ 1 and 8).

Note that the rejection of claims 51-53 and 56-57 under 102(b) does not give any patentable weight to the recitation of a "recombinant microorganism." This is because the recitation of "recombinant" does not impact the outcome of Applicants' method. In other words, Applicants' method simply functions to isolate glutaminase from a *Pseudomonad* regardless of whether the *Pseudomonad* is recombinant.

Assuming Roberts does not anticipate the invention based on the recitation of "recombinant," modifying Roberts to culture glutaminase from a recombinant microorganism would have been obvious in view of Olins. This results from the fact that Olins teaches enhancing the production of endogenous bacterial proteins by introducing the gene construct. According to Olins, the G10L gene construct can be used to enhance protein synthesis in a variety of *Pseudomonads* (*see* Expanded Example 2, col. 36 *et seq.*). Thus, one skilled in the art would have been motivated to modify Roberts with the teachings of Olins in order to increase the production of glutaminase. Moreover, such a combination would enjoy a reasonable expectation of success since Olin teaches that the G10L construct can be used to enhance protein production in various *Pseudomonads* (Table 1). Therefore, at the time of Applicants invention, it would have been obvious to one of ordinary skill in the art to modify Roberts with the teachings of Olin to arrive at the claimed invention.

Claims 51-53 and 56 are rejected under 35 U.S.C. 103(a) as obvious over "Smith" (J Biol Chem Vol. 286, No. 18 pp. 10601-10636).

Smith teaches a method of producing a therapeutically suitable glutaminase comprising transforming *E. coli* with glutaminase cDNA, isolating and characterizing the glutaminase cDNA, and expressing the glutaminase cDNA *in vitro* (p. 18975 and Fig. 3). Smith does not expressly teach collecting glutaminase from an *E. coli* expression system. However modifying Smith to include this step would have been obvious to one of ordinary skill in the art at the time of Applicants' invention. Smith motivates this combination because collecting glutaminase from an E. coli expression system would produce glutaminase enzyme in quantities sufficient to produce anti-glutaminase antibody (see p. 10632, ¶¶ 3-7). This is desirable because Smith uses anti-glutaminase antibody to identify glutaminase transformants. Moreover, the skilled artisan would have a reasonable expectation of success in collecting recombinant glutaminase from an *E. coli* transformant since Smith successfully transformed an *E. coli* with glutaminase cDNA.

Claim Objections

Claims 54 and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Rejection of Claims 51-57 under 35 U.S.C. 112, second paragraph

The rejection of claims 51-57 as being indefinite is withdrawn in view of Applicants' remarks.

Rejection of Claims 51-57 under 35 U.S.C. 102(b)

The rejection of claims as Anticipated by Ikura (JP 01300889) is withdrawn in view of Applicants' remarks. Applicants' remarks distinguish the claimed glutaminase from Ikura's glutaminase based on the fact that Ikura's glutaminase does not deplete glutamine. Applicants' remarks, and the

specification, note that the claimed glutaminase depletes glutamine. Hence, Ikura does not anticipate claims 51-57.

Conclusion

The prior art made of record a nd not relied upon is considered pertinent to applicant's disclosure: Katsumata et al. (US 4,560,661); Process for Purifying Enzymes (see Example 3); and Shapiro, R.A. Journ Biol Chem (October 1991) Vol. 266, pp. 18792-18796.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy M. Brown can be reached on (571) 272-0773. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

James C. Housel 4/4/05
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600